UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

OKLAHOMA FIREFIGHTERS PENSION AND RETIREMENT SYSTEM,	:	
Plaintiff,	:	Civil Action: No. 22-10200-WGY
v.	:	
	:	**LEAVE TO FILE GRANTED JULY 25, 2022**
BIOGEN INC., MICHEL VOUNATSOS, ALFRED SANDROCK, AND ALISHA ALAIMO,	:	
Defendants.	:	

CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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Dated: July 27, 2022

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PRELIMINARY STATEMENT

This case arises out of the unsuccessful commercial launch of ADUHELM™, Biogen Inc.'s ("Biogen") FDA-approved treatment for Alzheimer's disease. The drug's approval was the source of enormous hope for Biogen on behalf of patients and the company, and its unsuccessful launch the source of great disappointment. At no time did Biogen promise that the drug would be a commercial success. Plaintiff nevertheless seeks to recover for the decline in stock price in the seven months between FDA approval (June 7, 2021) and a proposal by the Centers for Medicare and Medicaid Services ("CMS") to limit Medicare coverage for the drug (January 11, 2022) by alleging that the defendants made false or misleading statements in that period. Plaintiff fails to state a claim and the case should be dismissed.

The Complaint[1] asserts violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78a et seq.) and Rule 10b-5 (17 C.F.R. § 240.10b-5) against Biogen, Michel Vounatsos (Biogen's CEO), Alfred Sandrock (Biogen's former Chief Medical Officer), and Alisha Alaimo, President of Biogen U.S. (the "Individual Defendants," and collectively with Biogen, "Defendants"). The Complaint is based principally on allegations that Defendants fraudulently misled the market regarding healthcare providers' and institutions' readiness to prescribe ADUHELM and the extent to which private and public insurance providers would pay for the costs of treatment. (*E.g.*, AC ¶ 16.) The Complaint, fails, however, to meet the statutorily heightened pleading requirements for a securities fraud suit provided for in the Private Securities Litigation Reform Act ("PSLRA"). Pursuant to the PSLRA and Federal Rules of Civil Procedure 12(b)(6) and 9(b), the Complaint should be dismissed with prejudice for the following independently dispositive reasons:

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[1] "AC" and "Complaint" refer to the amended Class Action Complaint, ECF No. 30.

First, Plaintiff does not plead adequately that any of Defendants' putative class period statements were false or misleading. (*Infra* Section I.) The Complaint identifies twenty-five statements contained in earnings calls and investor conference transcripts that allegedly misled investors, but none are actionable.[2] For example, Plaintiff challenges eight statements concerning Biogen's discussions with third-party payors and others about ADUHELM's price, alleging that those statements "suggest[ed]" that third-party payors had "approved, acquiesced, or at the very least indicated a willingness" to pay the price that Biogen ultimately set for the treatment (approximately $56,000 per year). (*See* AC ¶¶ 188, 191, 193, 231, 237.) But those statements "suggest" no such thing—they provide only that Biogen engaged in discussions with payors and others about ADUHELM's price and ultimately decided itself on a price that it determined was fair. (AC ¶ 188.)

Second, Plaintiff fails to plead particularized facts demonstrating a "strong inference" of scienter with respect to any challenged statement. (*Infra* Section II.) The Complaint relies principally on allegations attributed to eight alleged former employees, but none are alleged to have communicated the alleged facts to the Individual Defendants or to have identified someone else who did, and none of their statements are sufficient to establish scienter or support a strong inference of scienter. The allegations are generalized statements that are replete with vague adjectives and adverbs and lack the specificity that the First Circuit requires for allegations attributed to confidential witnesses to be sufficient under the PSLRA to establish the elements of a claim. For example, Plaintiff alleges that Defendants' estimate that approximately 900 healthcare sites across the United States would be ready to treat patients with

[2] Exhibit A attached hereto lists the challenged statements, contextual statements omitted from the Complaint that immediately precede or immediately follow each challenged statement, and the reasons why each statement is not actionable as a matter of law.

ADUHELM following FDA approval were false or misleading because two former employees reportedly observed (in their geographic territory) that "*many* potential treatment sites" and "*many* hospitals and clinics" were not ready. (AC ¶¶ 91, 108 (emphasis added).) Adjectives cannot substitute for specific factual allegations showing falsity or scienter, and stripped of those adjectives, the "facts" attributed to the former employees are not contrary to Defendants' public statements. Furthermore, Plaintiff's scienter allegations that are not based on former employees are equally deficient to establish a strong inference of scienter.

BACKGROUND[3]

Biogen is a global biotechnology company that researches, develops and markets treatments for serious neurological diseases, including ADUHELM. (AC ¶ 38.) ADUHELM is a monoclonal antibody treatment that reduces amyloid beta in the brain, a defining pathology of Alzheimer's disease. (AC ¶ 39.) Research shows that reduction of amyloid beta is a potential avenue for the prevention and treatment of neurological decline from Alzheimer's disease. (AC ¶ 39.) More than ten years ago, Biogen began studying ADUHELM as a treatment for Alzheimer's disease and initiated Phase 3 trials in 2016. (AC ¶¶ 52-53.)

A. Biogen And The FDA Evaluate The ADUHELM Phase 3 Clinical Trial Data

The Phase 3 clinical trials specified that a futility analysis be conducted during the trials. A futility analysis is a common tool to provide early warning that a trial is unlikely to

[3] Solely for purposes of this motion to dismiss, Biogen treats the allegations of the Complaint as true. In describing the relevant factual background, Defendants rely on documents referenced in the Complaint, matters of which the Court may take judicial notice, including public records and analyst reports, and documents incorporated into the Complaint. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Copies of such integral documents are included in the accompanying Appendix of Public Records (cited as "Tab __"), submitted herewith.

achieve its endpoints, which can be used to cease trials and avoid needless testing on humans. (*See* AC ¶ 54.) The futility analysis on ADUHELM was conducted by outside experts independent of Biogen and in March 2019, they recommended that Biogen terminate the two Phase 3 trials based on the probability that the final analysis would not show statistical significance in favor of ADUHELM. (AC ¶¶ 54-55.) On March 21, 2019, Biogen publicly announced the discontinuation of the Phase 3 trials based on the futility analysis. (AC ¶ 55.)

Biogen and its scientific team subsequently further evaluated the data from the Phase 3 trials and concluded that the results of the futility analysis were incorrect. (AC ¶ 59.) From June 2019 through October of 2019, representatives of Biogen and the FDA met regularly to discuss ADUHELM. (AC ¶ 58.)

B. After Examining The Clinical Trial Data The FDA Approves ADUHELM For The Treatment Of Alzheimer's Disease

In October 2019, Biogen announced that it intended to file an application with the FDA for approval of ADUHELM and completed its submission in July 2020. (AC ¶¶ 59-60.) As part of this announcement Biogen noted that "[t]he Phase 3 EMERGE Study met its primary endpoint showing a significant reduction in clinical decline, and Biogen believes that results from a subset of patients in the Phase 3 ENGAGE Study who received sufficient exposure to high dose aducanumab support the findings from EMERGE." (AC ¶ 59; Tab 1 at 1.) On November 6, 2020, the FDA's Peripheral and Central Nervous System Drug Advisory Committee (which is made up of outside advisors to the FDA) found by a vote of 10-0, with one member abstaining, that the Phase 3 trials did not present primary evidence of ADUHELM's efficacy. (AC ¶ 67.)

Notwithstanding the Advisory Committee's views, on June 7, 2021, the FDA approved ADUHELM for the treatment of Alzheimer's disease, through the FDA's accelerated approval pathway. (AC ¶ 84.) In approving the drug, the FDA stated:

> We examined the clinical trial findings with a fine-tooth comb, we solicited input from the Peripheral and Central Nervous System Drugs Advisory Committee, we listened to the perspectives of the patient community, and we reviewed all relevant data. We ultimately decided to use the Accelerated Approval pathway—a pathway intended to provide earlier access to potentially valuable therapies for patients with serious diseases where there is an unmet need, and where there is an expectation of clinical benefit despite some residual uncertainty regarding that benefit. In determining that the application met the requirements for Accelerated Approval, the Agency concluded that the benefits of ADUHELM for patients with Alzheimer's disease outweighed the risks of the therapy.

(Tab 8 at 2-3 (cited in AC ¶ 243 and quoting FDA Press Release).)

C. Biogen Evaluates Healthcare Sites To Determine Their Capability, Infrastructure, Education And Willingness To Treat A Patient With A Potential New Alzheimer's Therapy

In preparation for ADUHELM's potential approval and commercial launch, Biogen engaged with healthcare sites across the country to determine the extent to which sites would be "ready" to implement ADUHELM treatment in the event of FDA approval. (*E.g.*, AC ¶ 62.) As Ms. Alaimo informed investors on June 8, 2021, Biogen deemed a site "ready" if it had "the required capability, infrastructure, education and, most importantly, willingness to treat a patient with a potential new Alzheimer's therapy." (AC ¶ 174 (emphasis omitted).) Information to assess whether a healthcare site had sufficient capability, infrastructure, education, and willingness to treat a patient with a potential new Alzheimer's therapy was collected by Biogen employees designated "Alzheimer's Account Managers." (AC ¶ 62.) These Biogen employees used database systems to collect site data and assess site readiness along a number of metrics. (AC ¶¶ 64-65.) The reports shown to Biogen supervisors and executives

concerning sites that were deemed ready "utilized a simple red (not ready) to green (ready) color-coded system." (AC ¶ 66.)

D. ADUHELM's Commercial Launch

ADUHELM's approval immediately became the subject of controversy. ADUHELM's mechanism of action and underlying clinical data were questioned. (*See* AC ¶¶ 206, 208, 212.) In addition, press coverage negatively characterized the FDA's interactions with Biogen leading up to ADUHELM's approval. (AC ¶¶ 216, 225.) In an effort to address the misinformation and misunderstanding, on July 22, 2021, Dr. Sandrock, Biogen's Head of Research and Development, posted on Biogen's website an open letter to the Alzheimer's disease community. (Tab 8; AC ¶ 243.) In that letter, Dr. Sandrock commented on the "extensive development, testing and review process," during which "[Biogen] responded to numerous questions and requests from the FDA," and also commented that ADUHELM's approval was "supported by data of more than 3,000 patients and 2.2 million pages of clinical data and analyses." (Tab 8 at 1-2; AC ¶ 243.)

Nevertheless, ADUHELM's commercial launch continued to face substantial challenges including, in January 2022, a proposal by CMS to sharply limit Medicare coverage for ADUHELM. (AC ¶¶ 249, 269.) On January 11, 2022, CMS issued a draft National Coverage Determination ("NCD") proposing to limit reimbursement of FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease only to patients enrolled in a clinical trial.[4] (AC ¶ 269.)

[4] An NCD is process used by CMS to determine the circumstances under which it will reimburse the costs of an item or service. *See* https://www.cms.gov/Medicare/Coverage/DeterminationProcess.

In April 2022, CMS issued a final coverage determination sharply restricting coverage of ADUHELM and future drugs directed against amyloid for the treatment of Alzheimer's disease. Due to the restrictions on coverage, in May 2022 Biogen announced that it would substantially eliminate its commercial infrastructure supporting ADUHELM. (AC ¶ 273.)

E. Plaintiff's Allegations

Following CMS' issuance of its draft NCD in January 2022, Biogen's stock fell (AC ¶ 270) and this lawsuit quickly followed. Plaintiff challenges twenty-five statements made between June 7, 2021 through September 9, 2021, principally concerning ADUHELM commercialization efforts. These statements can be grouped into the following categories: (1) three statements concerning Defendants' estimate that over 900 healthcare sites were ready to implement treatment with ADUHELM following FDA approval (AC ¶¶ 170, 172, 174), (2) seven statements concerning potential obstacles in diagnosing patients with Alzheimer's disease (AC ¶¶ 176, 179, 228, 234, 239, 252, 255), (3) three statements concerning Medicare coverage (AC ¶¶ 181, 185, 193, 213), (4) eight statements concerning discussions with third-party payors (AC ¶¶ 188, 191, 193, 231, 237), (5) three statements concerning a potential agreement with the Veterans Health Administration ("VA") to provide ADUHELM to veterans (AC ¶¶ 196, 198), and (6) one statement contained in Dr. Sandrock's open letter to the Alzheimer's disease community allegedly describing Biogen's interactions with the FDA (AC ¶ 243).

Plaintiff also devotes 15 paragraphs (AC ¶¶ 60, 69-70, 72-74, 77-83, 96, 113) to statements made before the putative class period. However, pre-class period statements are not actionable. *See In re Garrett Motion Inc. Sec. Litig.*, No. 20 Civ. 7992 (JPC), 2022 WL 976269, at *15 (S.D.N.Y. Mar. 31, 2022) ("A defendant is liable only for those statements made during

the class period.") (citation omitted); *see also Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1217 n.31 (1st Cir. 1996).

ARGUMENT

To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5(b), Plaintiff must plead: (i) a material misrepresentation or omission; (ii) scienter; (iii) a connection with the purchase or sale of a security; (iv) reliance; (v) economic loss; and (vi) loss causation. *Metzler Asset Mgmt. GmbH v. Kingsley*, 928 F.3d 151, 158 (1st Cir. 2019); *see also ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008). Securities fraud pleadings are also subject to the rigorous requirements of Rule 9(b) and the PSLRA. Rule 9(b) requires that the circumstances constituting the fraud be stated "with particularity." Fed. R. Civ. P. 9(b). Under the PSLRA, Plaintiff must "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1)(B). Plaintiff must also allege with particularity specific facts giving rise to a "strong inference" of scienter. *Id.* § 78u-4(b)(2)(A).

I. THE COMPLAINT SHOULD BE DISMISSED IN ITS ENTIRETY BECAUSE IT DOES NOT ADEQUATELY ALLEGE THAT ANY STATEMENT WAS FALSE OR MISLEADING

A complaint brought under Section 10(b) must plead *specific facts* showing why the statements or omissions were false or misleading. 15 U.S.C. § 78u-4(b)(1); *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 193 (1st Cir. 1999). As set forth below, the Complaint fails to plead the requisite specific facts demonstrating that any of the challenged statements were false or misleading, warranting dismissal.

A. Statements Regarding The Number Of Healthcare Sites Ready To Implement ADUHELM

Plaintiff challenges three statements made in June 2021 expressing Defendants' estimate that more than 900 treatment sites were "ready"[5] to treat patients with ADUHELM shortly after FDA approval. (*See* Ex. A, entries 1, 3, 9; AC ¶¶ 170, 172, 174.) Plaintiff alleges that those statements were false or misleading because certain of the former employees referenced in the Complaint ("FEs") state that "many sites" were not ready and "many sites" were bulk coded as ready even though they were not individually evaluated. (AC ¶ 173.) The FE statements are not alleged with the specificity required by the PSLRA.

First, the Complaint alleges that FE 1 and FE 2 made non-specific statements that Biogen's site readiness data included "inaccuracies" and that there were "discrepancies" between what that data showed and how it was portrayed in Biogen's public statements. (AC ¶¶ 91-93, 108-10.) Those allegations—attributed to two FEs whose work was limited to the "mid-western part of the country" (AC ¶¶ 86, 103)—do not attempt to quantify the scope of the purported "inaccuracies" or "discrepancies" at the national level that would render Defendants' 900-site estimate misleading. In fact, the allegations fail to describe any specific "inaccuracies" or "discrepancies" in Biogen's data. The allegations do not specify which or how many sites in their particular territory (if any) that were allegedly not "ready" were included in the 900-site estimate and thus rendered that estimate incorrect; indeed, stating that "many sites" were not ready does mean that Defendants' 900-site estimate was false or misleading. *Cf. In re Biogen Inc. Secs. Litig.*, 857 F.3d 34, 42 (1st Cir. 2017) (affirming dismissal of securities complaint and

[5] As noted above, Ms. Alaimo informed investors that "ready means that [the sites] have the required capability, infrastructure, education and, most importantly, willingness to treat a patient with a potential new Alzheimer's therapy." (AC ¶ 174 (emphasis omitted).)

rejecting former employee statements that "do not even begin to quantify the magnitude of the sales decline at the company level").

Second, also insufficient are allegations attributed to FEs 1, 2, 4, 6, 7, and 8 concerning the coding of treatment sites administered by the VA. (AC ¶¶ 95, 97, 99, 112, 115, 134, 140, 158.) According to the FEs, they were "instructed" to code all VA administered sites ready, even though the FEs did not themselves believe that those sites were ready because VA sites had a "no contact" policy during COVID and they were not able to visit and evaluate them. (AC ¶¶ 97, 112, 134, 140.) Importantly, none of the FEs allege that their managers or any Defendant did not believe that those sites were ready. As Plaintiff acknowledges, Mr. Vounatsos and Ms. Alaimo publicly discussed their negotiations with the VA for a multiyear agreement (AC ¶¶ 196, 198), demonstrating that Biogen personnel at levels higher than any FE were in contact with the VA. Conspicuously absent from the Complaint are specific allegations demonstrating that the VA sites instructed to be coded "ready" were not in fact ready. Moreover, the FEs do not quantify the scope of the bulk coding of VA administered sites, including how that would impact Defendants' statements.

In short, the Complaint fails to allege the requisite specific facts showing why Defendants' statements that more than 900 sites were ready were false or misleading when made.

B. Statements Regarding Diagnosing Patients With Alzheimer's Disease

Plaintiff challenges seven statements addressing efforts at diagnosing patients with Alzheimer's disease. (*See* Ex. A, entries 2, 10, 18, 20, 22, 24, 25; AC ¶¶ 176, 179, 228, 234, 239, 252, 255.) Plaintiff alleges that those statements were false or misleading because Defendants omitted to tell investors that physicians and facilities were "extremely reluctant" to use lumbar punctures to confirm an Alzheimer's diagnosis, and that reluctance led to obstacles in prescribing ADUHELM. (AC ¶ 178.) Plaintiff does not allege that Defendants' actual

statements, which did not concern physician or facility reluctance to use lumbar punctures, were incorrect.

First, four of the seven statements merely describe a program Biogen established in partnership with Labcorp and Mayo Clinic Laboratories to assist physicians and patients in accessing cerebrospinal fluid ("CSF") diagnostic laboratory testing to aid in the diagnosis of Alzheimer's disease. (AC ¶ 176, 179, 234, 239.) Plaintiff does not allege that those statements were untrue, and its allegation that physicians were "reluctant" to order lumbar punctures does not make statements about the partnership in any way false or misleading.

Second, the three other alleged "false" statements concern slowness in scheduling and coordinating diagnostic tests and obtaining test results before treatment with ADUHELM. (AC ¶¶ 228, 252, 255.) Plaintiff's allegation that Defendants did not inform investors of alleged reluctance to order lumbar punctures is of no moment, because Defendants never said anything about the reluctance or lack of reluctance of physicians or facilities to use lumbar puncture testing. Rather, Defendants' merely stated that testing was "taking time to schedule and coordinate" and sites are "experienc[ing] several operational issues." (AC ¶¶ 228, 252.) Plaintiff's allegations do not show those statements to be false or misleading.

C. Statements Regarding Medicare Coverage

Plaintiff challenges two statements by Mr. Vounatsos and Ms. Alaimo in June 2021, stating that for patients with Medicare fee-for-service plans, coverage of treatment with ADUHELM "is automatically presumed with" FDA approval. (Ex. A, entries 5, 12; AC ¶¶ 181, 185.)[6] Plaintiff alleges that those statements are false or misleading because they "gloss[ed] over

[6] The Complaint also purports to challenge a statement from a Guggenheim analyst that references Medicare coverage for Aduhelm. (*See* AC ¶ 289 (citing paragraphs in the Complaint that identify challenged statements, including paragraph 213; *id.* ¶ 213 (citing Guggenheim

a complex regulatory process which could have potentially limited reimbursements for Aduhelm in a variety of ways, including one that ultimately substantially restricted Medicare's coverage for treatment," and that they "omitt[ed] to reveal even the possibility of a NCD being initiated." (AC ¶¶ 182-84, 186.)

Plaintiff fails to meet the pleading standards of the PSLRA. Mr. Vounatsos and Ms. Alaimo only stated that there was a presumption of coverage, not that coverage would ultimately be guaranteed.[7] A reasonable investor would have understood this distinction. Indeed, Biogen analysts understood the difference. Immediately following the conference call, analysts included in their analysis of ADUHELM's prospects questions about potential avenues CMS could take with respect to covering the treatment costs associated with ADUHELM, reflecting that they (and the market) understood the possibility that the costs of a covered treatment might not be reimbursed under certain circumstances. (*See, e.g.*, Tab 4 (6/14/2021 UBS Analyst Report at 1) (reflecting "discussion on how CMS might handle reimbursement for Medicare" and "anticipat[ing] a range of possibilities," including an NCD); Tab 5 (6/18/2021 UBS Analyst Report at 5-6) (discussing possibility of "pushback from Medicare" on covering costs of ADUHELM treatment).)[8] A statement is not misleading where market analysts

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analyst report); Ex. A entry 17.) Of course, an analyst statement cannot be attributed to the Defendants and, even if it could, that statement is not alleged adequately to be false or misleading for the reasons discussed above.

[7] Indeed, "presumption" is defined as to "an attitude or belief dictated by probability." *Presumption*, *Merriam-Webster's Collegiate Dictionary* (11th ed. 2020).

[8] Analyst reports may be considered. *In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) ("Judicial notice can be taken of . . . press releases[,] news articles and published analyst reports in determining what the market knew."); *In re Karyopharm Therapeutics Inc., Secs. Litig.*, 552 F. Supp. 3d 77, 91 n.1 (D. Mass. 2021) (taking judicial notice of contemporaneous analyst report in dismissing securities claim).

objectively understood the facts being conveyed. *See, e.g.*, *Born v. Quad/Graphics, Inc.*, 521 F. Supp. 3d 469, 485-86 (S.D.N.Y. 2021) (dismissing claim and finding, "[t]he Court's inability to infer that the statements were misleading is bolstered by contemporaneous statements by market analysts: [t]hey readily understood" the statement in its proper context).

D. Statements Regarding Third-Party Payors' "Approval" Of ADUHELM's Pricing

Plaintiff challenges eight statements regarding the process through which Biogen arrived at the price that it set for ADUHELM and the expectation of third-party payor coverage of the costs of treatment. (*See* Ex. A, entries 4, 7, 8, 11, 15, 16, 19, 21; AC ¶¶ 188, 191, 193, 231, 237.) Plaintiff alleges that the statements "suggest" that "Biogen had advanced communications with Medicare and other public and private payers and that those entities had approved, acquiesced, or at the very least indicated a willingness to pay the $56,000 per patient, per year price." (AC ¶¶ 189, 194.) But those statements do no such thing. The statements provide only that Biogen engaged with and received input from payors and others, and ultimately arrived at a price that it considered fair. (AC ¶ 188.) *Nowhere* in *any* of the allegedly misleading statements is there any suggestion that Medicare, or other public or private payers, had "approved," "acquiesced," or "indicated a willingness" to pay the price Biogen ultimately set for ADUHELM. Plaintiff's allegations are not supported by the statements themselves. *See Chun v. Fluor Corp.*, No. 3:18-CV-01338-X, 2021 WL 1788626, at *7 (N.D. Tex. May 5, 2021) (finding statements not false or misleading where plaintiff mischaracterized statements and that defendants "never said" what plaintiff alleged).

E. Statements Regarding Agreement With The Veteran's Health Administration

Plaintiff challenges three statements regarding Biogen's efforts to "finalize a multiyear agreement" with the VA to provide access to ADUHELM treatment for veterans. (*See*

Ex. A, entries 6, 13, 14; AC ¶¶ 196, 198.) Plaintiff alleged that the statements were false and misleading because (i) according to a former employee, a single "key opinion leader" within the VA was "opposed to including Aduhelm in the VA's formulary" in March 2021 (*i.e.*, three months before the commercial launch) and (ii) the process for determining whether VA sites were ready to administer ADUHELM was incomplete. (AC ¶¶ 197, 199.) Nowhere in the Complaint, however, does Plaintiff allege that Defendants' statements made were false—*i.e.*, nowhere does Plaintiff allege that there was anything false or misleading about Defendants' statement that Biogen "engaged[] with" and was "finalizing a multiyear agreement with" the VA (AC ¶¶ 196, 198). Nor does Plaintiff allege that any FE stated that Biogen was not in fact engaged in negotiations with the VA; indeed, none of the FEs are alleged to have made any statements at all concerning the contract negotiation with the VA.

F. Statement In Dr. Sandrock's Open Letter To The Alzheimer's Disease Community

In a July 22, 2021, open letter to the Alzheimer's disease community published on Biogen's website, Dr. Sandrock wrote, among other things (the Complaint quotes only the emphasized portions of the letter and misleadingly omits the sentences appearing before and after (AC ¶ 243)):

> Unfortunately, ADUHELM's approval has been the subject of extensive misinformation and misunderstanding. *It is normal for scientists and clinicians to discuss data from experiments and clinical trials, to debate, and to disagree, on the interpretation of data*. That is how science advances and we welcome these discussions. *Recently, however, there has been a turn outside the boundaries of legitimate scientific deliberation*.

(Tab 8 at 1; cited at AC ¶ 243 (emphases added).) Regarding ADUHELM efficacy and safety data, Dr. Sandrock wrote:

> *Separately, we have seen statements that ADUHELM's results are 'post-hoc' – in other words that a filter was applied after the fact to interpret data in a certain way. That is also factually incorrect*. The primary and secondary endpoints had

> been prespecified in the Phase 3 trial protocols, before the first patient was enrolled into the trials. The ADUHELM label shows the results on these pre-specified endpoints, based on data that had already been collected at the sites by the time the trials were prematurely terminated on March 21, 2019. . . .
>
> *It is important to recognize that collaboration between industry and regulatory agencies is common, appropriate and beneficial*. That was exemplified best with the COVID-19 vaccine development. As a doctor, a scientist and the Head of Research and Development at Biogen, I believe scientists at regulatory agencies and drug manufacturers must work together in an effort to defeat other devastating public health threats.

(Tab 8 at 2; cited at AC ¶ 243 (emphases added).)

Plaintiff alleges that Dr. Sandrock's "statement that Biogen's interactions with the FDA to resurrect ADUHELM was appropriate and not out of the ordinary was materially false and misleading" because Acting FDA Commissioner Woodcock allegedly "conceded that there have been contact between the FDA and Biogen 'outside the formal correspondence process.'" (AC ¶ 244.) Plaintiff mischaracterizes both Dr. Sandrock's and Ms. Woodcock's statements.

First, Plaintiff misconstrues Dr. Sandrock's statements. Nowhere does Dr. Sandrock comment on any particular interactions between Biogen and the FDA. (Tab 8; cited at AC ¶ 243.) Rather, Dr. Sandrock's statements are general and non-specific, expressing only his belief that collaboration between industry participants and regulatory agencies is common, appropriate and beneficial, and that "scientists at regulatory agencies and drug manufacturers must work together in an effort to defeat other devastating public health threats." (Tab 8 at 2; cited at AC ¶ 243.) Indeed, the Complaint misleadingly takes the emphasized language above from different parts of the letter, rearranges those snippets in a different order, and from that rearrangement concludes that Dr. Sandrock stated that "Biogen's interactions with the FDA to resurrect Aduhelm was appropriate and not out of the ordinary." (AC ¶¶ 243-44.) That is of course improper pleading and should be rejected as such.

Second, Plaintiff mischaracterizes and misquotes Acting Commissioner Woodcock's statement. Acting Commissioner Woodcock did not, as Plaintiff states, "concede[] there have been contact between the FDA and Biogen 'outside the formal correspondence process.'" (AC ¶ 244.) Rather, Ms. Woodcock stated that the OIG should conduct an investigation about whether there were any interactions that were inconsistent with FDA policies and procedures:

> There continue to be concerns raised, however, regarding contacts between representatives from Biogen and FDA during the review process, including some *that may have* occurred outside of the formal correspondence process. . . . I believe that it is critical that the events at issue be reviewed by an independent body such as the Office of the Inspector General *in order to determine whether* any interactions that occurred between Biogen and FDA review staff were inconsistent with FDA policies and procedures.

(Tab 7; cited at AC ¶¶ 218, 244 (emphases added).)

In short, reviewing the statements in context reveals that Dr. Sandrock made no false or misleading statements as a matter of law.[9]

II. THE COMPLAINT SHOULD BE DISMISSED IN ITS ENTIRETY FOR THE INDEPENDENT REASON THAT IT DOES NOT ALLEGE SPECIFIC FACTS SUPPORTING A "STRONG INFERENCE" OF SCIENTER

Scienter is a "conscious intent to defraud" or "a high degree of recklessness." *ACA Fin.*, 512 F.3d at 58 (citation omitted). Recklessness means a "highly unreasonable omission, involving not merely simple, or even inexcusable[] negligence, but an extreme departure from the standards of ordinary care." *In re Biogen Inc. Sec. Litig.*, 193 F. Supp. 3d 5, 44 (D. Mass. 2016), *aff'd*, 857 F.3d 34 (1st Cir. 2017) (alteration in original) (citation omitted).

[9] The Complaint appears to identify a statement by Mr. Vounatsos during a September 9, 2021 Morgan Stanley Global Healthcare Conference (AC ¶ 249) as false or misleading. (*See id.* ¶ 289.) The Complaint, however, is completely silent as to how or why that statement could be considered false or misleading, and the statement is therefore not actionable.

Scienter must be evaluated on a statement-by-statement basis. 15 U.S.C. § 78u-4(b)(2)(A). To plead scienter, Plaintiff must "with respect to each act or omission . . . state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." *Id.* (emphasis added). "To qualify as 'strong,' 'an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" *LSI Design & Integration Corp. v. Tesaro, Inc.*, No. 18-cv-12352-LTS, 2019 WL 5967994, at *3 (D. Mass. Nov. 13, 2019) (citations omitted). Courts "must weigh not only inferences urged by the plaintiff but also competing inferences rationally drawn from the facts alleged." *Whitehead v. Inotek Pharms. Corp.*, No. 17-cv-10025-LTS, 2018 WL 4732774, at *3 (D. Mass. June 27, 2018) (citation omitted).

Complaints satisfying the pleading standard for scienter frequently include "clear allegations [of admissions], internal records, or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendants were aware that they were withholding vital information" or at least warned by others that this was so. *Mahoney v. Found. Med., Inc.*, 342 F. Supp. 3d 206, 213 (D. Mass. 2018) (citation omitted); *see also In re Bos. Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012). Such knowledge must be alleged to have been had *contemporaneously* with the allegedly false statements; *after-acquired* awareness and allegations of fraud by hindsight do not suffice. *In re Ariad Pharms., Inc. Secs. Litig.*, 842 F.3d 744, 751-52 (1st Cir. 2016).

As noted, Plaintiff challenges six categories of statements as false or misleading. (*See supra* Background, Section E.) As detailed below, the Complaint fails to allege a strong inference of scienter with respect to any of those challenged statements.

A. The Complaint Fails To Allege A Strong Inference Of Scienter With Respect To Statements Concerning (i) Healthcare Site Readiness, (ii) Diagnosing Patients With Alzheimer's Disease, (iii) Third-Party Payor Discussions, And (iv) An Agreement With The VA

Plaintiff's case with respect to statements concerning (1) the number of healthcare sites estimated to be ready, (2) diagnosing patients with Alzheimer's disease, (3) third-party payor discussions, and (4) the negotiation of a potential agreement with the VA exclusively rely on averments from the eight former Biogen employees. In the First Circuit, "there must be a hard look at [former employee] allegations to evaluate their worth." *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 51 (1st Cir. 2008). This "hard look" requires such allegations to comply with the heightened pleading requirements of the PSLRA, and a court to "evaluate . . . factors such as 'the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations . . . and similar indicia.'" *Local No. 8 IBEW Ret. Plan v. Vertex Pharms. Inc.*, 140 F. Supp. 3d 120, 127 n.5 (quoting *N.J. Carpenters*, 537 F.3d at 51). The requisite "hard look" at the allegations attributed to the former employees in this case demonstrates that those allegations fail to give rise to any inference of scienter with respect to any challenged statements as a matter of law.

1. Dismissal Is Warranted Because The Former Employees Were Not Senior Management, And Are Not Alleged To Have Had Any Contact With Any Individual Defendant

In *In re Biogen Inc.*, the First Circuit affirmed dismissal of a securities complaint where—as here—plaintiffs' theory of fraud principally relied upon statements attributed to former employees. In doing so, the First Circuit held that statements attributed to former employees "are 'not described with sufficient particularity' . . . to give rise to a strong inference of scienter as to senior management *if none of the witnesses were senior managers and they had*

little contact with such managers." 857 F.3d at 43 (emphasis added) (citation omitted). Similarly here, the allegations attributed to the FEs cannot give rise to the requisite strong inference of scienter because the Complaint itself makes plain that those FEs did not have reporting relationships with an Individual Defendant, and does not allege that they had contact with any Individual Defendant.

Plaintiff's witness allegations originate from eight non-leadership former employees (*see* AC ¶¶ 85-164) who are not described with sufficient particularity and are so far removed from Biogen's senior management that the allegations attributed to them cannot plausibly support an inference of scienter:

	Title	**Alleged Responsibilities And Location**	**Employed**	**Reported To**
FE 1	Alzheimer's Account Manager (AC ¶¶ 86-102)	Educated and evaluated ADUHELM treatment sites in the "mid-western part of the country" (AC ¶ 86)	04/2020 to 05/2022 (AC ¶ 86)	*No reporting line alleged at all, let alone to any Defendant*
FE 2	Alzheimer's Account Manager (AC ¶¶ 103-19)	Educated and evaluated ADUHELM treatment sites in the "mid-western party of the country" (AC ¶ 103)	*Not alleged*	*No reporting line alleged at all, let alone to any Defendant*
FE 3	Access and Reimbursement Manager (AC ¶¶ 120-28)	Evaluated infusion site assessments in Central California and Las Vegas, Nevada (AC ¶ 120)	10/2020 to 11/2021 (AC ¶ 120)	Director of Access and Reimbursement (at least 4 levels removed from "senior Biogen leadership") (AC ¶ 121)
FE 4	Director of Account Liaisons (AC ¶¶ 129-40)	Oversaw Account Liaisons; reviewed clinical, financial and operational preparedness of health systems in their territory (AC ¶¶ 129, 131); *location not alleged*	03/2020 to 04/2021; *not employed during the putative Class Period* (AC ¶ 129)	Senior Director of Alzheimer's Account Liaisons (at least 4 levels removed from Ms. Alaimo) (AC ¶ 130)
FE 5	Senior Territory Business Manager (AC ¶¶ 141-50)	Clinical sales of ADUHELM (AC ¶ 141); *location not alleged*	08/2020 to 01/2022 (AC ¶ 141)	*No reporting line alleged at all, let alone to any Defendant*

	Title	**Alleged Responsibilities And Location**	**Employed**	**Reported To**
FE 6	Territory Business Manager (AC ¶¶ 151-54)	Clinical sales of ADUHELM in Boston area (AC ¶ 151)	08/2020 to 02/2022 (AC ¶ 151)	*No reporting line alleged at all, let alone to any Defendant*
FE 7	Senior Territory Business Manager (AC ¶¶ 155-58)	Clinical sales of ADUHELM (AC ¶ 155); *location not alleged*	08/2020 to 03/2022 (AC ¶ 155)	Regional Manager (at least 5 levels removed from Ms. Alaimo) (AC ¶ 155)
FE 8	Senior Territory Business Manager (AC ¶¶ 159-64)	Clinical sales of ADUHELM in the Mid-Atlantic (AC ¶ 159)	08/2020 to 03/2022 (AC ¶ 159)	*No reporting line alleged at all, let alone to any Defendant*

None of the FEs are alleged to have been a member of Biogen's "senior management," *In re iRobot Corp. Secs. Litig.*, No. 19-cv-12536-DJC, 2021 WL 950675, at *10 (D. Mass. Mar. 12, 2021), and none are alleged to have directly reported to any of the Individual Defendants (or even to have reported to anyone who themselves reported to an Individual Defendant). In addition, none of the FEs are alleged to have had *any* contact with any Defendant, let alone any communications or reporting relationship. *See In re iRobot*, 2021 WL 950675, at *10 (fact that confidential witnesses had little or no ongoing contact with defendant's senior management "undercut[] the Plaintiffs' reliance upon them in the pleadings, particularly when the PSLRA requires that confidential witnesses allege 'with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind'") (quoting 15 U.S.C. § 78u-4(b)(2)(A)). In short, the allegations by the eight FEs lack the "specific descriptions of the precise means through which [the defendants' alleged fraud] occurred," *In re Biogen Inc.*, 857 F.3d at 43 (alteration in original) (citation omitted). This alone warrants dismissal of these categories of challenged statements.

Furthermore, and independent of the dispositive inadequacies associated with the FEs' roles and interactions, as discussed below, the FE statements themselves are equally insufficient to give rise to a strong inference of scienter.

2. Former Employee Statements About Site Readiness Do Not Give Rise To A Strong Inference Of Scienter

Plaintiff alleges that Defendants' June 2021 statements that Biogen estimated over 900 accounts ready (AC ¶¶ 170, 172, 174) were knowingly false or misleading based on deficient, conclusory allegations attributed to FEs 1, 2, 4, 6, 7, and 8 that there could not have been 900 sites ready. (AC ¶¶ 173, 175.) But the FE allegations regarding site readiness (AC ¶¶ 91-102, 108-119, 133-40, 152, 158, 162-63) are not alleged with specificity sufficient to show that any challenged statement was knowingly false, let alone establish a strong inference of scienter.

First, as discussed above (*see supra* Section I.A), the statements attributed to FEs 1, 2, 4, 6, 7, and 8 about alleged "inaccuracies" and "discrepancies" in site readiness data and receiving instructions to bulk code VA sites as "ready" are not alleged with the specificity required to render Defendants' statements to be false or misleading. For substantially the same reasons, those same FE statements are not sufficiently particular to give rise to a strong inference of scienter. For example, the allegations attributed to FE 1 and FE 2 are replete with vague adjectives and adverbs:

- "*many potential treatment sites* flat-out refused to move forward at all" (AC ¶¶ 91, 108 (emphasis added));
- "*many hospitals and clinics* will not put a treatment within their [list of treatments] . . . without . . . peer-reviewed data" (*id.* (emphasis added)); and
- "*Consistently, sites would partially* move forward with one aspect of the care pathway" (*id.* (emphasis added)).

"[Adjectives and] adverbs are not facts , and the addition of [adjectives and adverbs] . . . does not prove scienter." *Special Situations Fund III QP, L.P. v. Deloitte Touche Tohmatsu CPA, Ltd.*, 96 F. Supp. 3d 325, 344 (S.D.N.Y. 2015). Moreover, although both FE 1 and FE 2 claim that they

spoke to each other about these purported concerns (AC ¶¶ 92, 109), they do not make any specific allegations that employees in other parts of the country had similar concerns (AC ¶¶ 93, 110).

Second, none of the FEs claim that they ever spoke to any Defendant about any of their alleged concerns or observations. *See Meltzer*, 928 F.3d at 161 ("relevance [of confidential witness statements] is further diminished by the fact that the complaint does not allege that any of the CWs ever spoke with any of the individual defendants or otherwise shared with them their observations"). Although FE 1 and FE 2 claim that they raised concerns with "Biogen leadership" (AC ¶¶ 102, 119), they do not identify any such "leadership." Rather, FE 1 and FE 2 claim that they told a "Senior Director of Access and Reimbursement" in March 2021 (*three months before the alleged misleading statements*) that they believed that the determination of whether a site was ready "was far more complex," and it was their view that certain sites were not ready. (AC ¶¶ 94, 111.) But conspicuously absent from the Complaint are any details about that conversation, what the Senior Director said, or whether the Senior Director reported that information to anyone. The allegations are further undercut by FE 1 and FE 2's acknowledgment that Biogen conducted an internal inquiry into potential issues concerning site readiness coding. (AC ¶¶ 100, 116.) Missing from the Complaint, moreover, are any specific factual allegations about that investigation or its findings. The existence of the investigation cannot lead to the conclusion that any wrongdoing occurred.

Third, the FEs' conclusory allegations that Defendants must have been aware of inaccuracies with the 900-site estimate because they are alleged to have reviewed site readiness data is also insufficient to raise a strong inference of scienter. (AC ¶¶ 98, 114, 136-37.) It is not enough to allege that Defendants reviewed reports; instead, "one would need to know what [a

defendant] learned from such monitoring, and whether what he learned was at odds with any of his . . . statements." *Meltzer*, 928 F.3d at 162. No such allegations appear in the Complaint. To the contrary, Plaintiff alleges that "the reports generated (then rolled up to a national level) . . . and shown to supervisors and executives utilized a simple red (not ready) to green (ready) color-coded system. Those sites that were coded as green were deemed to be ready to administer [ADUHELM] very soon after its approval." (AC ¶¶ 66, 90, 107.) There are no allegations that those reports were at odds with what Defendants reported publicly.

Fourth, also insufficient to allege scienter are Plaintiff's allegations that statements made later during the putative class period constituted "admissions" that Defendants' earlier statements concerning 900 sites being "ready" were somehow false or misleading *when made*. (AC ¶¶ 228-29, 234-35, 252-53.) For example, Plaintiff cites to Mr. Vounatsos's statement in July 2021 that "[o]f the 900 sites approximately which we expected to be ready shortly after approval, we estimate that approximately 325 or 35% have completed a [Pharmacy & Therapeutics ("P&T")] review." (AC ¶ 228.) Plaintiff alleges that this statement was a "partial admission" that earlier statements in June 2021 that Biogen estimated "there are over 900 [sites] ready" (*i.e.*, have the required capability, infrastructure, education, and willingness to treat a patient (AC ¶ 174)) were misleading. (AC ¶ 229.) But Mr. Vounatsos's July 2021 statement about 35% of ready sites having completed P&T reviews is not contradictory to earlier statements that 900 sites have the required capability, infrastructure, education, and willingness to treat a patient. Similarly, Ms. Alaimo's statement three months later about P&T reviews (AC ¶¶ 252-53) does not contradict her earlier statements that 900 sites "have the required capability, infrastructure, education, and . . . willingness to treat a patient." (AC ¶ 174.) These later statements are not contradictory to the statements made by the Defendants and,

consequently, they cannot support an inference of scienter as a matter of law. *See In re Peritus Software Servs., Inc. Secs. Litig.*, 52 F. Supp. 2d 211, 223 (D. Mass. 1999) (holding that after-the-fact statements "do not by themselves suffice to show that the [alleged] misstatements occurred knowingly or recklessly.").

3. Former Employee Statements About Diagnosing Patients With Alzheimer's Disease Do Not Give Rise To A Strong Inference Of Scienter

Plaintiff challenges seven statements addressing efforts at diagnosing patients with Alzheimer's disease. (AC ¶¶ 176, 179, 228, 234, 239, 252, 255.) Plaintiff alleges that those statements were false or misleading because Defendants omitted to tell investors that physicians and facilities were "extremely reluctant" to use lumbar punctures to confirm an Alzheimer's diagnosis, and that reluctance led to obstacles in prescribing ADUHELM. (AC ¶ 178.) Plaintiff does not allege that the statements Defendants actually made (*e.g.*, that Biogen "established a program with Labcorp and Mayo Clinic Laboratories to help physicians and patients access CSF diagnostic laboratory testing to aid the diagnosis of Alzheimer's disease" (AC ¶ 176)) were false and stated with scienter. As discussed above, the statements are not false or misleading because Plaintiff's alleged omitted facts are unrelated to the statements themselves; Defendants never said anything about the reluctance or lack of reluctance of physicians or facilities to use lumbar puncture testing. (*See supra* Section I.B.) In addition to that dispositive failure, the Complaint also fails to allege any facts giving rise to a strong inference of scienter with respect to those statements.

First, Plaintiff alleges that Defendants knew that their statements were false or misleading because FEs 3, 5, 6, 7, and 8 claim that they observed physician reluctance to using lumbar punctures. As an initial matter, none of the FEs purport to claim that any of Defendants' statements were false or misleading in any way. In addition, the statements attributed to the FEs

are non-specific and conclusory. For example, FE 3 states that it was their "belief" that lumbar punctures caused a "bottleneck" in prescribing ADUHELM (AC ¶¶ 123-24), but nowhere does FE 3 describe with specificity the scope of any "bottleneck" or when the "bottleneck" was observed. Similarly insufficient are statements from (i) FE 5 that "a lumbar puncture was the 'no go' for doctors," (ii) FE 6 that there was "significant opposition" to using lumbar punctures, (iii) FE 7 that there was "significant resistance" to using lumbar punctures, and (iv) FE 8 that lumbar punctures "negatively impacted" ADUHELM performance. (AC ¶ 143, 153, 156, 161.) Like the statements attributed to FE 3, those statements are too non-specific and conclusory to support an inference of scienter.

Second, the FEs fail to allege that any of them spoke to any Defendant about these alleged issues. FE 3 states that "it was widely acknowledged within Biogen that the facilities performing the lumbar punctures were a major bottleneck," and also alleges that certain Biogen employees "intimated" that issues about bottlenecks were "conveyed to more senior managers." (AC ¶ 125.) Missing from those allegations, however, are *specific facts* about, who spoke to any Defendant, what was said, and when. Absent those requisite facts, the FE allegations cannot give rise to a strong inference of scienter as a matter of law. *See Metzler*, 928 F.3d at 162. The same result is warranted here.

4. Former Employee Statements About Third-Party Payors Do Not Give Rise To A Strong Inference Of Scienter

Plaintiff alleges that approximately eight statements made between June 2021 and July 2021 that Biogen has engaged with third-party payors regarding the cost of ADUHELM (AC ¶¶ 188, 191, 193, 231, 237) were knowingly false or misleading because FEs 1, 2, 3, 5, 6, and 8 allege that "*many* providers and public payors had expressly refused to make any commitments with respect to Aduhelm." (AC ¶¶ 189, 194 (emphasis added); *see also id.* ¶¶ 192,

233, 238.) But Plaintiff makes no allegation that any of the statements made by any Defendant was false, and also fails to allege a strong inference of scienter.

The Complaint does not make any allegations that any FEs had any responsibility or involvement with Biogen's contacts with third-party payors, or that any FE ever spoke to any Defendant about interactions with third-party payors (or that anyone else did so). Rather, the allegations attributed to the FEs are limited to interactions with health care providers and doctors. (*See* AC ¶¶ 91, 97, 99, 108, 115, 128, 145, 152, 161-62.) But the FE allegations have nothing to do with contacts with third-party payors, and therefore cannot support an inference of scienter with respect to statements that Biogen has engaged with third-party payors regarding the cost of ADUHELM.

5. Former Employee Statements About The VA's Capacity To Cover And Administer ADUHELM Do Not Give Rise To A Strong Inference Of Scienter

Plaintiff alleges that three statements made in June 2021 about Biogen "working to finalize a multiyear agreement" with the VA (AC ¶¶ 196, 198) were knowingly false or misleading because FEs 1, 2, 4, 6, 7, and 8 allege that certain "key opinion leaders" within the VA were opposed to ADUHELM and that VA sites were not open during COVID so therefore could not be evaluated. (AC ¶¶ 197, 199.) But there is no allegation that Biogen was *not* actually working with the VA to negotiate an agreement, and therefore the FE allegations cannot support an inference of scienter.

First, the allegation attributed to FE 4—who left Biogen two months before the beginning of the putative class period—are unrelated to the negotiation of a multiyear agreement with the VA. FE 4 states that *one* doctor affiliated with the VA Boston Healthcare System allegedly did not support ADUHELM (an opinion not even provided directly to this FE). (AC ¶ 140.) Although FE 4 asserts that they "knew" the VA would not include ADUHELM, they do

not explain how this *one* doctor could or would dictate a course of action for the entire VA. (*Id.*) Similarly, FE 4 does not allege that they, or anyone else, ever spoke to any Defendant about the doctor's concern. Indeed, there is simply no allegation that the statements about Biogen's negotiations with the VA were false. These allegations cannot support a finding of falsity or an inference of scienter.

Second, the allegations attributed to FEs 1, 2, 6, 7 and 8 about the coding of VA sites as ready fail for the same reasons as discussed above. (*See supra* Section I.A.) Moreover, similar to the allegations attributed to FE 4, those allegations are unrelated to the negotiation of a multiyear agreement with the VA, and therefore cannot support an inference of scienter with respect to those statements.

B. The Complaint Fails To Allege A Strong Inference Of Scienter With Respect To Statements About Medicare Coverage

Plaintiff challenges two statements where Defendants stated that for patients with Medicare fee-for-service plans, coverage of ADUHELM "is automatically presumed with FDA approval." (AC ¶¶ 181, 185.) Missing from the Complaint, however, are any allegations that would support an inference of scienter. There are no allegations that even purport to address Defendants' state of mind or to suggest that Defendants made the statements with a "conscious intent to defraud." *ACA Fin.*, 512 F.3d at 58 (citation omitted). Indeed, the Complaint is bereft of any scienter allegations whatsoever.

C. The Complaint Fails To Allege A Strong Inference Of Scienter With Respect To The Statement In Dr. Sandrock's Open Letter To The Alzheimer's Disease Community

Plaintiff challenges a statement contained in Dr. Sandrock's July 22, 2021 letter to the Alzheimer's disease community. (AC ¶ 243.) As discussed above, Plaintiff grossly misconstrues both the language and context of Dr. Sandrock's letter. (*See supra* Section I.F.)

Moreover, Plaintiff does not even attempt to show that Dr. Sandrock (or any other Defendant) did not believe every statement in that letter. The Complaint is bereft of any allegation supporting any inference of scienter, let alone the requisite strong inference.

D. A Nonculpable Inference Under *Tellabs* Is More Compelling Than Scienter

An inference of fraudulent intent must be "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Far more compelling than any inference of fraud is that Biogen believed in ADUHELM's potential to address a serious and unmet medical need and provide relief to millions of Americans suffering from Alzheimer's disease. Despite its optimism for ADUHELM's commercial prospects, unanticipated obstacles arose during the commercial roll-out of the treatment, and ADUHELM did not turn out to be the success that Biogen had hoped it would become. However, failing to accurately predict commercial setbacks is not securities fraud. *In re Genzyme Corp.*, Nos. 09-11267-GAO, 09-11299-GAO, 2012 WL 1076124, at *12 (D. Mass. Mar. 30, 2012), *aff'd*, 754 F.3d 31 (1st Cir. 2014) ("nonculpable explanation" that defendants "did not expect . . . the setbacks the company experienced" was "stronger" than culpable inference plaintiff alleged). The Complaint should be dismissed.

III. COUNT II SHOULD BE DISMISSED BECAUSE THERE IS NO PREDICATE EXCHANGE ACT VIOLATION

Without a viable primary violation of the Exchange Act, there is no basis to maintain a claim under Section 20(a). *See* 15 U.S.C. § 78t(a); *see also ACA Fin.*, 512 F.3d at 67 ("[t]he plain terms of [S]ection 20(a) indicate that it only creates liability derivative of an underlying securities violation"); *Vertex*, 140 F. Supp. 3d at 137. As there is no Exchange Act violation here, there can be no Section 20(a) liability.

CONCLUSION

For all of the foregoing reasons, Defendants' motion to dismiss should be granted, and the Complaint (ECF No. 30) dismissed with prejudice.

Dated: Boston, Massachusetts
July 27, 2022

Respectfully submitted,

/s/ James R. Carroll

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